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Date

Gina N. Shishima

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
An *et al.*

Serial No.: 09/966,762

Filed: September 28, 2001

For: NEW MOLECULAR TARGET FOR TREATMENT OF CANCER

Group Art Unit: 1642

Examiner: Ungar, Susan Nmn

Atty. Dkt. No.: UROC:033US

DECLARATION OF ROBERT W. VELTRI, Ph.D.

I, Robert W. Veltri, Ph.D., hereby declare as follows:

1. I am a U.S. citizen residing at 13705 Milbert Ridge Drive, Baldwin, MD 21013. I am an associate professor in the Department of Urology at the Johns Hopkins Hospital. I have extensive experience in cancer research. References containing examples of my work are included in my *Curriculum Vitae*. A copy of my *Curriculum Vitae* is attached as Exhibit 1.

2. I am one of the inventors named on the present patent application. I am also a co-author on An *et al.*, *Cancer Research* 60:7014-7020 (2000), which is cited by the Examiner in the Office Action dated May 12, 2004.

3. I have an understanding of the specification of the application, the Office Action dated May 12, 2004, and An *et al.*, *Cancer Research* 60:7014-7020 (2000).

4. I understand that the Examiner has rejected current claims 1, 3, 4, 6, 9-10, 12-14, 21-23, 25, 35, 37-38, 65, 67-69, and 71-72 of the application on the grounds that they are not enabled by the disclosure in the specification. In making this rejection, the Examiner asserts that the data provided in the specification does not establish that UC28 is overexpressed on the membranes of primary prostate cancer cells. I am providing this information to show that the present specification does establish that UC28 is overexpressed on the membranes of primary prostate cancer cells.

5. The present specification discloses that UC28 expression is upregulated in cancer tissues over normal and benign tissues (Specification, p. 79, ln. 21-22). The present specification also discloses that a significant portion of UC28 protein localizes to the cell membrane (Specification, p. 114, ln. 12-13). Localization of the UC28 protein on the cell membrane of prostate cancer cells was demonstrated in the C4-2B cell line using a rabbit polyclonal antibody produced against a UC28 synthetic peptide and visualized by fluorescent confocal imaging technology (Specification, p. 114, ln. 4-13).

6. The present specification discloses the amino acid sequence of the UC28 protein in SEQ ID NO: 2. Amino acids 34 to 50 of SEQ ID NO: 2 encode a putative transmembrane domain.

The presence of this putative transmembrane domain indicates that UC28 localizes to the cell membrane.

7. The Examiner cites An *et al.*, *Cancer Research* 60:7014-7020 (2000) as evidence that the UC28 protein is primarily located in the cytoplasm, and thus not on the membrane, of primary prostate cancer cells. As mentioned above, I am a co-author on the An *et al.* paper. While An *et al.* states that "UROC28 protein was localized primarily in the cyotoplasm of prostate and breast cancer glandular epithelial cells" (An *et al.*, p. 7017, col. 2), this does not contradict the disclosure in the present specification that a significant portion of UC28 protein localizes to the cell membrane.

8. An *et al.* characterized the distribution of UC28 in terms of nuclear localization versus cytoplasmic localization. This is evident when An *et al.* is read in context: "UROC28 protein was localized primarily in the cyotoplasm of prostate and breast cancer glandular epithelial cells (Fig. 5A-D). However, distinct nuclear localization of UROC28 protein was also noted in prostate cancer glandular epithelia (Fig. B)." An *et al.*, p. 7017, col. 2. The use of conventional fluorescence microscopy limited the ability of An *et al.* to more specifically characterize the localization of UC28. In the present specification, however, confocal microscopy was used to visualize UC28 on the cell membrane of prostate cancer cells. Confocal microscopy permits the user to obtain sharply defined optical sections that eliminate or reduce fluorescence away from the focal plane.

9. In conclusion, the present specification discloses that the expression of UC28 is upregulated in cancer tissues over normal and benign tissues, and that a significant portion of UC28 protein localizes to the cell membrane. The amino acid sequence of the UC28 protein

disclosed in SBQ ID NO: 2 contains a transmembrane domain, which indicates that the protein localizes to the cell membrane. Furthermore, the localization of the UC28 protein on the cell membrane was confirmed in the prostate cancer cell line C4-2B. Thus, the present specification discloses that UC28 is overexpressed on the cell membrane of prostate cancer cells as compared to normal prostate cells. Finally, the evidence presented in the specification is not refuted by An *et al.*

10. I declare that all statements made of my knowledge are true and all statements made on the information are believed to be true; and, further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issued thereupon.

Date: 11/12/04

Robert W. Veltri

Robert W. Veltri, Ph.D.

Exhibit 1 to Declaration of
Robert W. Veltri, Ph.D.

[October, 2004]

DEMOGRAPHIC INFORMATION

Current Appointments:
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Education and training (in chronological order):

B.A.	1961-63	Youngstown State University	Biology/Chemistry
M.S.	1963-65	West Virginia University	Microbiology
Ph.D.	1965-68	West Virginia University	Microbiology

Professional Experience (in chronological order):

Positions	Institutions	Dates
Assistant Professor & Director of Research	West Virginia University Medical School, Div. of Otolaryngology and Department of microbiology	1969-72
Associate Professor & Director of Research	West Virginia University Medical School, Div. of Otolaryngology and Department of microbiology	1972-75
Professor & Director of Research	West Virginia University Medical School, Div. of Otolaryngology and Department of microbiology	1975-81
Director of virology and special immunology fee for service WVU hospital diagnostic laboratory	West Virginia University Medical School and Department of Clinical Pathology	1972-81
Director of R&D;	Cooper- Biomedical, Inc., Malvern, PA	1981-84
Project Director	National Foundation for Cancer Research, Bethesda, MD	1981-86
President/CEO	American Biotechnology Company, Rockville, MD	1984-88
Executive Vice President & Chief Scientific Officer	Theracel, Inc., Rockville, MD	1988-90
Vice President of R&D & Chief Scientific Officer	CytoDiagnostics, Inc., OKC, OK.	1990-94

Vice President of R&D and General Manager of R&D	UroCor, Inc., OKC, OK.	1994-01
Adjunct appointee in the department of pathology	Oklahoma University Health Sciences Center, OKC, OK.	1994-01
Institutional Biosafety Committee	Oklahoma University Health Sciences Center, OKC, OK.	1997-01
Governor of State of Oklahoma Health Research Committee member	State of Oklahoma Center for Advancement of Science and Technology (OCAST)	1997-01
Biotechnology Advisory Committee	Oklahoma City Community College	1998-01
Biomedical Engineering Advisory Board of the Department of Engineering	University of Central Oklahoma	2000-01
Technical supervisor of UroCor Clinical Chemistry laboratory	UroCor, Inc.	2000-01
Visiting Associate Professor	Johns Hopkins University School of Medicine	2001-03
Associate Professor	Johns Hopkins University School of Medicine	2003-

RESEARCH ACTIVITIES:

1. Veltri RW and BE Kirk. An antiviral substance in the tissues of mice acutely infected with lymphocytic choriomeningitis virus. J Gen Virol., 10(1):17-27, 1971.

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4. Veltri RW and PM Sprinkle. Serous otitis media. Immunoglobulin and lysozyme levels in middle ear fluids and serum. Ann Otol Rhinol Laryngol., 82(3):297-301, 1973.

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90. Veltri RW, Ph.D., M. Craig Miller. B.S., Gerard J. O'Dowd. M.D., and Alan W. Partin, M.D., Ph.D. Impact of Age on Total and Complexed PSA Cutoffs in a Contemporary Referral Series of Men with Prostate Cancer. *Urology* 60 (Suppl 4A): 47-52, 2002.

91. Sawczuk IS, Cynthia L. Pickens, Usha R. Vasa, David A. Ralph , Ph.D., Kathy A. Norris, M. Craig Miller, B.S., Angela Y. Ng, H. Barton Grossman, and Robert W. Veltri. DD23 Biomarker: A Prospective Clinical Assessment In Routine Urinary Cytology Specimens From Patients Being Monitored For TCC. *Urologic Oncology* 7: 185-190, 2002.

92. Gilbert SM, A Shabsigh, Sawczuk A, U Vasa, Angela Ng, C Pickens, K Norris, S Bright, GJ O'Dowd, MC Benson, CA Olsson, AS Sawczuk and RW Veltri,. Evaluation of DD23 as a marker for detection of recurrent transitional cell carcinoma (TCC) of the bladder in patients with a history of bladder cancer. *Urology* 61: 539-543, 2003.

93. Veltri, RW, Leonard S. Marks, M. Craig Miller, Wes D. Bales, John Fan, Maria Luz MaCairan, Jonathan I. Epstein, and Alan W. Partin. Saw Palmetto Alters Nuclear Measurements Reflecting DNA Content In Men With Symptomatic BPH: Evidence For A Possible Molecular Mechanism. *Urology* 60: 617-22, 2002.

94. Veltri, Robert W., Manisha Chaudhari , M Craig Miller , Edward C. Poole, Gerard J. O'Dowd and Alan W. Partin. Comparison of Logistic Regression and Neural Net Modeling for Prediction of Prostate Cancer Pathologic Stage. *Clin Chem.* 48(10): 1828-34, 2002.

95. Ellison LE, Cheli C, Bright S, Veltri RW, and Partin AW. Cost-benefit analysis of total PSA, Free/Total PSA and complexed PSA for prostate cancer screening. *Urology* 60 (Suppl 4A): 42-46, 2002.

96. Haese A, Chaudhari M, Miller MC, Epstein JI, Graefen M, Hammerer P, Palisaar J, Huland H, Poole EC, O'Dowd GJ, Partin AW, and Veltri RW. Quantitative biopsy pathology for the prediction of pathologically organ confined prostate cancer: A multiinstitutional validation study. *Cancer* 97: 969-78, 2003.

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98. Gretzer MB, Alan W Partin, Daniel W Chan, and Robert W. Veltri. Modern Tumor Marker Discovery in Urology: Surface Enhanced Laser Desorption and Ionization (SELDI). *Reviews in Urology*, 5(2): 81-89, 2003.

99. Khan MA, Alan W. Partin, Harry G. Rittenhouse, Stephen D. Mikolajczyk, Lori J. Sokoll, Daniel W. Chan, and Robert W. Veltri. Evaluation of Pro-PSA for the Early Detection of Prostate Cancer in Men with a total PSA Range of 4.0-10 ng/ml. *J Urology* 170: 723-726, 2003.

100. Khan MA, H. Ballentine Carter, Jonathan I. Epstein, Michael C. Miller, Patricia Landis, Patrick C. Walsh, Alan W. Partin and Robert W. Veltri. Can PSA derivatives and pathological parameters predict significant change in expectant management criteria for men with prostate cancer? *J Urology* 170: 2274-78, 2003.

101. Khan MA, Patrick C. Walsh, Michael C. Miller, Wesley D. Bales, Jonathan I. Epstein, Leslie A. Mangold, Alan W. Partin and Robert W. Veltri. Quantitative alterations in nuclear structure predict prostate cancer distant metastasis and death in men with biochemical recurrence post-radical prostatectomy. *Cancer,* 98: 2583-9, 2003.

102. Park Jae, Lori J. Sokoll, Debra J. Bruzek, Leslie Mangold, Robin Gurganus, Masood A. Khan, Alan W. Partin, Daniel W. Chan, and Robert W. Veltri. Comparison of total PSA and derivative levels in a screening population of African-American, Caucasian, and Korean-American men. *Clinical Prostate Cancer,* 2: 173-76, 2004.

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104. Veltri RW, Alan W. Partin, and M. Craig Miller. Quantitative Nuclear Grade (QNG): The clinical applications of the quantitative measurement of nuclear structure using image analysis. In: Cancer Drug Discovery and Development. Gary J. Kelloff, Ernest T. Hawk and Caroline C. Sigman, Eds. *The Humana Press Inc.*, Totowa, NJ, *Chapter 6*, 97-108, 2004. (In Press).

105. Gretzer MB, Daniel W Chan, C. L. van Rootselaar, J.M. Rosenzweig, S. Dalrymple, L.A. Mangold, Alan W Partin, and Robert W. Veltri. Proteomic analysis of Dunning Prostate Cancer Cell Lines with Variable Metastatic Potential using SELDI-TOF. *Prostate.* 60:(4):325-31, 2004.

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107. Marks LS, Kojima M, Demarzo A, Heber D, Bostwick DG, Qian J, Dorey FJ, Veltri RW, Mohler JL, Partin AW. Prostate cancer in native Japanese and Japanese-American men: Effects of dietary differences on prostatic tissue. *Urology*, 64(4):765-71, 2004.

108. Rogers CG, MA Khan, MC Miller, RW Veltri, and AW Partin. Natural history of progression in patients who fail to achieve an undetectable PSA following radical prostatectomy. *Cancer*, (In Press), 2004.

INVENTIONS, PATENTS, COPYRIGHTS (pending awarded):

1. Szent-Gyorgyi A, Fodor G, Veltri RW. 2-Furylbutyrolactone derivatives, their preparation, compositions containing them, and their use for modulation of the immune system in mammals. *Patent No. 4,518,611; Issued: May 21,1985*. Assigned to Theracel Corp., Rockville , MD.
2. Veltri RW, Maxim PE, Fodor G. 2-Furylbutyrolactone modulation of the immune system in mammals. *Patent No. 4,518,611 Issued 05-21-85*. Assigned to Theracel Corp., Rockville, MD.
3. Maxim PE and Veltri RW. Assaying for circulating immune complexes with labeled protein A. *Patent No. 4,617,262, Issued October 14, 1986.* Assigned to CooperBiomedical Inc., Palo Alto, CA.
4. Veltri, RW and Maxim PE. Method of treating inflammation in mammals utilizing ketobutyrolactones and furylbutyrolactones. *Patent No. 4,883,813, Issued November 28, 1989*. Assigned to Theracel Corp., Rockville, MD.
5. Fodor G, Sussangkarn K. and Veltri RW. Condensation products of cyclic diketones and ascorbic acid as immunomodulatory agents. *Patent No. 4,883,808 Issued 11-28-89*. Assigned to Theracel Corp., Rockville, MD.
6. Fox, SW and Veltri RW. Microencapsulated antitumor agent. *Patent No. 4,963,364, Issued October 16, 1990.* Assigned to the inventors.
7. Veltri RW, Fodor G, and Sussangkarn K. Pharmaceutically useful furyl substituted dihydroxyethylbutyrolactones. *Patent No. 5,102,909 issued 04-07-92*. Assigned to Theracel Corp., Rockville, MD.
8. Veltri RW and Fodor G. Pharmaceutically useful Michael addition products of unsaturated aldehydes and ketones and ascorbic acid. *Patent No. 5,098,933 issued 03-24-92*. Assigned to Theracel Corp., Rockville, MD.
9. An G, O'Hara SM, Ralph DA and Veltri RW. Biomarkers and targets for diagnosis, prognosis and management of prostate disease. *Patent No. 5,882,864 Issued 03-16-1999*. Assigned to UroCor, Inc., Oklahoma City, OK.
10. Gang An and Robert W. Veltri Biomarkers and targets for diagnosis, prognosis and management of prostate diseases. *Patent No. 5,972,615. Issued October 26, 1999*. Assigned to UroCor, Inc., Oklahoma City, OK.
11. Gang An, Veltri RW et al Biomarkers and targets for diagnosis, prognosis and management of prostate, breast, and bladder cancer. *Patent Number 6,218,529* issued on 4/1/2001., Assigned to UroCor, Inc., Oklahoma City, OK.
12. Garry M. Marley and R.W. Veltri. Method for Selectively Inducing Biomarker Expression in Urologic Tumor Tissue for Diagnosis and Treatment Thereof. *Patent No. 5,856,112 Issued 01-5-1999*. Assigned to UroCor, Inc., Oklahoma City, OK.
13. Veltri RW, Miller MC, Bacus MP, Ashenayi K. A sextant core biopsy predictive mechanism for non-organ-confined disease status". Issued November 23, 1999. *Patent No. 5,989,811, Issued 09-29-2000*. Assigned to UroCor, Inc., Oklahoma City, OK.
14. Robert W. Veltri, Michael P. Bacus, M. Craig Miller. Prediction of Prostate Cancer Progression by Analysis of Selected Biomarkers. *Patent No. 6,025 126, Issued 02-15-2000*. Assigned to UroCor, Inc., Oklahoma City, OK.
15. Gang An and RW Veltri. A novel, prostate-specific gene for diagnosis, prognosis and management of prostate cancer. *Patent No. 6,156,515 Issued December 5, 2000*. Assigned to UroCor.
16. Ralph DA, An G, and Veltri RW. Diagnosis of disease state using mRNA profiles in peripheral leukocytes. *Patent No. 6,190,857 issued February 20, 2001*. Assigned to UroCor, Inc., Oklahoma City, OK.
17. An, Gang and Veltri, Robert. Prostate-specific gene for diagnosis, prognosis and management of prostate cancer. *Patent No.* 6,369,195 *Issued April 9, 2002.* Assigned to UroCor, Inc., Oklahoma City, OK.

INVENTIONS, PATENTS, COPYRIGHTS (pending awarded):

18. Veltri, Robert W., Ashenayi, Kaveh, Hu, Ying and O'Dowd, Gerard J. Neural network for cell image analysis for identification of abnormal cells. ***Patent No. 6,463,438 issued October 8, 2002.*** Assigned to UroCor, Inc., Oklahoma City, OK.
19. Veltri RW. *Trademark*, "**UroScore™**". Serial No. 7468233 registered January 16, 1996 to UroCor Inc., Oklahoma City, OK. Registration No. 1948820 for Laboratory research services in the field of oncology.
20. Veltri RW. *Trademark*, Quantitative Nuclear Grade "**QNG™**". Serial No. 76173213 registered March 19, 2002 to UroCor Inc. of Oklahoma City, OK. Registration No. 2549632 for Medical services for detecting, staging, and prognosis of cancer.

Extramural Sponsorship (current, pending):

FUNDED SPONSORED RESEARCH:

"Evaluation of *UROC28* serum biomarker for early detection of prostate cancer." Proposed dates are April 1, 2003 through March 31, 2004. The proposal is in collaboration with an EDRN member, Dr. Alan W. Partin. $100,000 (Total for grant period – 1 year). I am the P.I. for the project and received Associate Membership in the EDRN. 35% effort. Started April 1, 2003.

"Epidemiology and significance of bladder cancer in areas endemic for *Shistosoma haematobium* in Africa". P.I. from JHU School of Public Health is Clive Schiff, Ph.D. Total Direct Costs for my role as co-investigator = $11,415.50. I have a 2.5% commitment to the grant. Started September 2003.

"Phase II trial of soy prior to radical prostatectomy". NIH is the sponsor and the program I.D. number is PAR-03-055 Quick-Trials for novel cancer therapies. P.I. from NYU is Maarten Bosland, DVSc, Ph.D. Total direct costs = $500,000; Current year direct costs = $250,000; Co-investigator at 5% effort and Direct costs for my project in year 1 are $21,453. Project to start April 1, 2004.

PENDING SPONSORED RESEARCH: None

PREVIOUS SPONSORED RESEARCH:

West Virginia University School of Medicine:

"Etiopathogenesis of recurrent serous otitis media." 1971-74; Deafness Research Foundation; Total award = $33,000; P.I. and 25%.

"Search for new human lung tumor associated antigens." 1974-78; National Cancer Institute Research Contract NO1-CB-43890. Total award = $422,909; P.I. at 25%.

"Lewis lung carcinoma immunotherapy model". 1976; American Cancer Society; total award = $2,544; P.I. at 5%.

"Epstein-Barr virus effects on the immune system." 1977; American Cancer Society; totals award =$2,550; P.I. at 5%.

"Clinical and viral studies of sudden hearing loss." 1978-81; NIH 1-R01-NS-15629-01; William Wilson M.D. (Massachusetts General Hospital) and Robert W. Veltri, Ph.D. (WVU), Co-principal investigators); Total award to WVU = $73,074.
"Immunomodulatory factors in head and neck cancer." 1981-83: National Cancer Institute 1-RO1-CA37390-01; Total award $148,000; P.I. 25% commitment. This NCI grant was transferred from WVU to industry (CooperBiomedical Inc.) in 1981.

American Biotechnology Co. (Theracel Corporation)

"Cloning and propagation of human tumor cells on interfaces of oil microcarrier emulsions." 1985-86; Topic 46; NIH-SBIR-Phase I; Co-P.I. with Dr. Ivar Giaver, Ph.D. at General Electric, Inc. $50,000.

"Effect of MFBLs on monokine and lymphokine production." 1985-86; Topic 29; NIH-SBIR Phase I; Baseler, M, Veltri RW and Maxim PE Co-Principal investigators; $50,000.

"Development of new synthetic immunoaugmentive agents." 1985-86; Topic 29; NIH-SBIR Phase I; Veltri RW, Baseler M and Maxim PE, Co-Principal Investigators; $50,000.

"Effect of MFBL on B-lymphocyte function." 1985-86; Topic 29; NIH-SBIR Phase I; Maxim PE, Veltri RW, and Baseler M, Co-Principal Investigators; $50,000.

"Antiviral efficacy of butyrolactone immunomodulators." 1988; Topic N87-4; Navy-SBIR Phase I; Veltri RE and PE Maxim Co-P.I.s; $50,000.

"Antiviral efficacy of butyrolactone immunomodulators." 1988-90; Topic N-87-4; N00014-89-C-0021; Veltri RE and PE Maxim Co-P.I.s; 25% commitment; $500,000.

CytoDiagnostics Inc. (UroCor Inc.)

"Nuclear matrix proteins and actin: biomarkers for cancer." 1992; Topic 12-L; Veltri RW and Briggman JL Co-P.I.s; $50,000.

"Neural networks to detect and classify bladder cancer" 1992; Veltri RW (P.I.) with RE Hurst of Oklahoma University Health Sciences Center and Kaveh Ashenayi of Tulsa University Department of Electrical Engineering (Co-investigators); $50,000.

"Combined use of tissue morphology, neural network analysis of chromatin texture and clinical variables to predict prostate cancer aggressiveness from biopsy material." 1998-00; Partin AW (P.I.) and Veltri RW (Co-investigator and subcontractor). Total direct costs for UroCor over 2.5 years was approximately $130,000.

"Diagnostic soluble urine test for interstitial cystitis." 1998-99; Veltri RW (P.I.); SBIR Phase I grant No. 1R43-DK53150-01A1; $100,000.

"Development of solution-phase Methylation Specific PCR to amplify and detect methylated target genes in isolated genomic DNA." 1999-00; An, Gang (P.I. and Veltri RW (Co-P.I.); SBIR Phase I grant No. 1 R43 CA90007-01; $100,000.

"Diagnosis and prognosis of prostate cancer using multiplex RT-PCR." 1999-00; An, Gang (P.I. and Veltri RW (Co-P.I.); SBIR Phase I grant No. 1 R43 CA83607-01; $100,000.

"p53 mutational analysis for bladder cancer prognosis." June 2000-May 2002; Ralph DA and James Prescott (Co-P.I.s) and Veltri RW (Co-investigator); SBIR Phase II No. 2 R44 CA76823-02Total award $693,828. Dr. Veltri served as the grant fiscal and technical administrator also assisted in obtaining IRB approval and setting up the IRB approved multi-site (Six) clinical trials for the project. The project was completed by Dr. James Prescott (New P.I.) after Dr. Veltri left in November, 2001.

UNDERGRADUATE AND GRADUATE TEACHING:

1968-72 - Nursing microbiology Course #26

1972-81 – Medical Microbiology Course #301, Virology Section consisting of 14 lectures, 4 labs and 2 clinical programs.

1975-77 – Course coordinator for the Medical Microbiology #301 course for medical students.

1972-81 – Clinical Laboratory Virology 491, four hours credit for graduates students in microbiology.

1974-81 – Basic Microbiology II Course No. 317-A. A six credit course. Dr. Veltri taught 2 credits of the six credit course dealing with the mechanisms of pathogenesis of viral diseases.

1970-81 - WVU continuing medical education lecturer for Neurology, Internal Medicine, Otolaryngology, Oncology, and Dentistry.

1972-81 – Established and sustained the WVU Sigma Xi Research Society multidisciplinary competitive graduate student research convocation and awards program.

1970-81 – A total of 19 Medical and Dental students rotated through my research laboratories on summer research fellowships for periods of time average 10-12 weeks.

1970-81 – Course Instructor at the annual meeting of the American Academy of Ophthalmology and Otolaryngology (AAOO) with Phillip M. Sprinkle, M.D. (Chairman of Otolaryngology) Course was entitled "Clinical immunology and Infectious Diseases in Otolaryngology".

***GRADUATE MENTORING**: 1970-83 - (primary advisor):*

James McClung, 1973-75; MS in microbiology; Thesis: "Epstein-Barr virus in human tonsil derived lymphocytes".

William Wainwright, 1973-75; MS in microbiology; Thesis: "Isolation and identification of early antigen complex from lymphoblastoid cell lines."

Louis Heyl, 1974-76; M.S. in microbiology; Thesis: "Epstein-Barr virus genome carrying lymphocyte subpopulations."

Maria Urquilla, 1974-76; M.S. in microbiology; Thesis: "In vitro production of soluble lung tumor associated antigens."

John McKolanis, 1975-77; M.S. in microbiology; Thesis: "Antigenic studies of the murine Lewis Lung tumor; An animal model for lung cancer."

Valerie A. Kikta, 1976-79; M.S. in microbiology; Thesis: Mechanism of action of serum blocking factor (SBF) isolated from infectious mononucleosis sera."

John L. Sloyer, 1970-72; Ph.D. in microbiology; Dissertation: "Immunobiology of human tonsil derived lymphocytes in vitro."

Lee Tuckwiller, 1972-79; Ph.D. in microbiology; Mechanisms of immunity in Herpes Simplex virus infections of man."

William Wainwright, 1975-80; Ph.D. in microbiology; Dissertation: "Immune regulatory mechanisms associated with Epstein-Barr infectious mononucleosis."

John R. McKolanis, 1977-80; Ph.D. in microbiology; Dissertation: "Immune response to a solublized membrane antigen of murine Lewis Lung Carcinoma."

Kenneth Dowler, 1980-82; Ph.D. in microbiology; Dissertation: "Fc receptors on the surface of Herpes Simplex viruses Types 1 and 2."

R. Scott Fritz, 1980-83; Ph.D. in microbiology; Dissertation: "Immunological investigations with monoclonal antibody specific for Lewis Lung tumor associated membrane antigen."

EDITORIAL ACTIVITIES (Reviewer)

British Journal of Cancer

Cancer Epidemiology, Biomarkers, and Prevention.

Cancer

Cancer Research

Clinical Cancer Research

Clinical Prostate Cancer

J Urology

Molecular Genetics and Metabolism

The Prostate

Urology

ORGANIZATIONAL ACTIVITIES:

Institutional Administrative Appointments:

1974-76 – WVU Foundation Fellowship Committee.

1974-81 – Clinical Cancer Education and Cancer Committee.

Professional Societies:

1973-75 – Treasurer WVU Chapter of Sigma Xi.

1976-77 – President WVU Chapter of Sigma Xi.

1978 – Member at large, West Virginia American Cancer Society Board of Directors.

1978-80 – Board of Directors, Monongalia County Chapter of the West Virginia Chapter of the American Cancer Society. Also, Public Speaking Chairman from 1979-80.

1985 – Secretary-Treasurer, Association of Biotechnology Companies, Washington, DC (Bruce Mackler, Ph.D. and J.D.; President and co-founder).

Membership: AACR, FASEB (AAI), ASM, American Academy of Microbiology, AUA, AAAS, AACC, Society for Basic Research in Urology (SBUR).

Conference Session Chair;

Invited by Dr. Ronald Berezney to chair a session for the FASEB summer conference meeting on "Nuclear Structure in Cancer" to be held in Saxton River, VT June 7-12, 2003.

Advisory Committees and Review groups:

2003 - Appointed to serve on the NIH/NCI SPORE Biomarker Development Working Group by Jorge Gomez, Chief, Organ Systems Branch, National Cancer Institute.

2003- Appointed to serve on the NIH/NCI INTERPROSTATE Biomarkers Study (IPBS) Group by Jorge Gomez, Chief, Organ Systems Branch, National Cancer Institute.

2003 Served on the NCI Genitourinary SPORE review committee – April 26-28, 2003.

2002-05 - Serving on the External Advisory Committee for the NIDDK BPH-MTOPS Prostate Samples Analysis (mPSA) consortium project (2002-2005).

1982 - Advisor to the National Committee for Clinical Laboratory Standards (NCCLS), Area Ligand Committee on Immunology and Ligand Assays.

Consultantships:

1971-74 – Immunology and microbiology consultant to Dr. Lee Brown of the **Dental Branch, Texas Medical Center**, University of Texas, Houston, TX. Project 1 was a NASA contract to monitor immune function and microbiological changes in astronauts in the Skylab project and Project 2 was a NCI research contract investigating dental caries etiology in Head and Neck cancer patients undergoing radiation therapy.

1985-86 – Consultant to Michael K. Ullman, Senior V.P. of **Cooper Development Inc.**, Therapeutics Division, Menlo Park, CA. The company was working on liposomes as a drug delivery system for cancer drugs.

Consultantships (Continued):

1987-88 – Consultant to **Mylan Pharmaceuticals** regarding the technical data for a submission of a potential FDA approved composition of matter (small molecule) for a new use as an anti-HIV agent to the FDA. I was responsible for analytical assessment of all pre-clinical antiviral data and preparation of a final report and recommendation.

2000 – Served as a consultant to **Qiagen** at a two day meeting. I served as a member of an Advisory Panel to review existing and new molecular-based technologies in development and also provided a lecture on the UroCor Inc. non-isotopic RNase Protection Assay (NIRCA) to assess mutations in p53 in urine samples of patients being monitored for bladder cancer recurrence.

2000 – August 1, 2000 I served as a consultant to JoAnn Boland and Dan McLaurin of **Becton-Dickenson**, diagnostics division, to review their Melastatin-DIG probe in-licensed from Millennium Pharmaceuticals. Their intent is to release an Analyte Specific Reagent (ASR) early in 2001. I reviewed the technical R&D data files and attended an Advisory Board meeting on the subject. A written technical report was also filed.

2000-01 – I served as a consultant to **Baylor College of Medicine Technologies** (BSMT) group. I evaluated the pre-clinical technology, which was to serve as a basis for a new start up in the area of prostate cancer therapeutics. The start-up Company is to be called Progression Therapeutics Inc. (PSi) and utilizes technology that originated in the BCM. I reviewed the entire technology and filed a go-no go report. Next, I assisted in preparing the back ground for the technical component of a business plan. This consultantship was approved by the JHU Conflict of Interest Office and the Department of Urology.

2001– 03 - Served as a speaker for the **Bayer Corporation**, Diagnostics division, in the area of PSA testing. I provided a total of six lectures during the year to urologists, pathologists and clinical chemistry laboratory specialists throughout the United States. This consultantship was approved by the JHU Conflict of Interest Office and the Department of Urology.

2003- Served as a speaker and consultant to the **GenProbe** scientific advisory board to review Molecular Oncology as a new diagnostic business opportunity.

RECOGNITION:

Awards and honors:

1976 – WVU School of Medicine outstanding teacher award

1979 – Elected a Fellow of the American Academy of Ophthalmology and Otolaryngology

1981 – Visiting professor of microbiology at the University of Chile in Santiago from July 28-August 8, 1981. I was one of three faculty members that taught a course in

viral oncogenesis and tumor immunology. My portion of the course consisted of eleven lectures, two seminars, and three laboratory sessions. Also, the faculty made me an honorary member of the Chilean Society of Microbiology.

1975-76 – President of the WVU Chapter of Sigma Xi, a research honorary. Initiated a interdisciplinary research competition in science for graduate students in the sciences.

2001 – Certificate of Recognition from Governor Keating for his services in helping to advance science and technology in Oklahoma presented by Dr. William A Sibley, President of Oklahoma Center for the Advancement of Science and Technology (OCAST) on October 30, 2001. Also a letter of appreciation was included from Dr. Kathy Kocan on behalf of the Health Research Committee.

Invited Talks and Panels:

1999 – Invited speaker at the Workshop on Chemoprevention of Prostate Cancer held August 8-9, 1999 in Baltimore, MD. Conference chairman was Ronald Lieberman, M.D. My talk was entitled *"Computer-assisted analysis of predictive factors and potential new biomarkers and methods for chemoprevention of prostate cancer."* A manuscript resulted from this presentation: Veltri RW, Miller MC, and An G. Standardization, analytical validation, and quality control of intermediate endpoint biomarkers. *Urology* **57(Suppl 4A)**, 164-70, 2001.

2000 – Invited participant in the Superficial Bladder Cancer State of the Science (SOTS) Workshop held September 21-22, 2000 in Bethesda, MD. I participated in two breakout groups; Group A on Diagnostics/Markers/Endpoints and Group B Relapse and Progression, Therapeutics strategies and chemotherapy and Immunotherapy.

2001 - Principal speaker at the summer FASEB summer conference on "Nuclear Structure and Cancer" co-chaired by Drs. Garry S. Stein, Ronald Berezney and Robert Getzenberg and held in Saxtons River, VT August 11-16, 2001. Lecture was entitled "Quantitative Nuclear Grade (QNG): A new image analysis-based biomarker of clinically relevant nuclear structure alterations." A manuscript resulted from this presentation: Veltri, RW, Partin, AW, and Miller, MC. Quantitative nuclear grade (QNG): A new image analysis-based biomarker of clinically relevant nuclear structure alterations. *J. Cellular Biochemistry*, **35**: (Suppl), 151-157, 2000.

2001 – Invited speaker at the 2001 MDACC "Tumor Markers: A new Era" meeting held from March 3-5, 2000 in Santa Barbara, CA. I conducted a roundtable session entitled *" Bladder Cancer Cytology Biomarkers for Detection and Monitoring: An Overview."* Dr. Herbert Fritchie was the meeting organizer and coordinator.

2002 – Invited principal speaker at the 34th Oak Ridge Conference sponsored by the AACC and held April 25-26, 2002 in San Diego, CA. The title of my presentation was "A comparison of logistic regression statistical and artificial neural network modeling for prediction of prostate cancer pathologic stage." This presentation resulted in a manuscript published in: *Clin Chem.* 48(10):1828-34, 2002.

2003 - Principal speaker at the summer FASEB summer conference on "Nuclear Structure and Cancer" co-chaired by Drs. Ronald Berezney and Robert Getzenberg and held in Saxtons River, VT June 7-12, 2003. I chaired a Workshop entitled " Clinical Studies of Nuclear Structure and Cancer" and gave one of the lectures. The lecture was entitled "Nuclear morphometric image analysis: New applications in urological cancer."

Invited Reviews and Editorials:

1998 – A special issue of *Seminars in Urologic Oncology* dedicated to "Prognostic factors for Prostate Cancer", Alan W. Partin, M.D., Ph.D., Guest Editor. I was an invited

participant in the issue that was built around a single case report. My contribution was: Veltri, *RW*, GO O'Dowd, R. Orozco, M. Craig Miller, The Role of Biopsy Pathology, Quantitative Nuclear Morphometry, and Biomarkers in the Pre-operative Prediction of Prostate Cancer Staging and Prognosis. *Seminars in Urologic Oncology*, 16(3): 106-107, 1998.

Invited Reviews and Editorials:

1999 – Editorial - Invited to write a response to the article by A. de la Taille, Carl A. Olsson and Aaron E. Katz entitled "Molecular staging of prostate cancer: Dream or Reality"., Oncology 13: 187-94, 1998. My editorial was on 205 and 209.

2002 – An invited author for a special supplement of *Urology* dedicated to complexed PSA. I was invited to submit one article and served as a co-author on a second article. The articles were: 1) Veltri RW, Ph.D., M. Craig Miller. B.S. , Gerard J. O'Dowd. M.D., and Alan W. Partin, M.D., Ph.D. Impact of Age on Total and Complexed PSA Cutoffs in a Contemporary Referral Series of Men with Prostate Cancer. *Urology* 60 (Suppl 4A): 47-52, 2002 and 2) Ellison LE, Cheli C, Bright S, Veltri RW, and Partin AW. Cost-benefit analysis of total PSA, Free/Total PSA and complexed PSA for prostate cancer screening. *Urology* 60 (Suppl 4A): 42-46, 2002.

2003 – Prepared a invited review for Volume 2 ["Strategies for Cancer Chemoprevention:] of a two volume series entitled **"Cancer Chemoprevention"** being published by Humana Press and the Editors are Drs. Gary J. Kelloff, Ernest T. Hawk, and Caroline C. Sigman. My chapter is entitled *"Quantitative Nuclear Grade: The clinical applications of the quantitative measurement of nuclear structure using image analysis."*

OTHER PROFESSIONAL ACCOMPLISHMENTS:

From 1969-80 Dr. Veltri served on the faculty of microbiology and surgery of WVU, where his applied research included virology, immunology, and cancer biomarkers. Dr. Veltri developed a fee for service clinical immunology and virology diagnostic testing service for the WVU hospital's department of clinical pathology that generated about $100,000 in revenue by 1980. Teaching responsibilities included medical, dental, nursing and graduate level students in areas of microbiology, virology, and cancer biology. He also trained and served as advisor for six MS and six Ph.D. graduate students of microbiology during his tenure at WVU. A total of seventeen Medical, Dental, and Medical Technology students did research clerkships in Dr. Veltri's laboratory during his tenure at WVU. He obtained more than $1.0 Million in extramural research funding while at WVU.

In 1981-84 Dr. Veltri established an R&D team, which developed the first diagnostic application for liposomes that consisted of rapid (1-2 minutes) and sensitive (10-fold improvement to ng/ml) slide co-agglutination diagnostic kits for infectious and rheumatologic diseases. Three Class II, FDA approved 510K products were transferred to manufacturing and released to market based upon a proprietary and patented co-agglutination technology that employed a proprietary method to prepare protein-A coated Liposomes and combine them with antibody coated latex particles. The three FDA approved tests were for Streptococcal Group A, Rheumatoid arthritis, and Infectious Mononucleosis.

In 1984, Dr. Veltri founded the American Biotechnology Company in Rockville, MD (acquired by Theracel Corporation in 1988). We discovered two unique classes of L-Ascorbic acid derivatives based upon the use of an Aldol and Michael addition series of modifications performed at the C-2 position of the molecule (see patents 1,2,4,5, 7 and 8 above). These small molecules were all of very low toxicity, water-soluble and

demonstrated a variety of biological activities including anti-cancer, anti-infectious and anti-inflammatory activity.

OTHER PROFESSIONAL ACCOMPLISHMENTS:

In 1996, Dr. Veltri and his R&D team commercialized the first statistical-based (Logistic Regression model) and patented algorithm to predict prostate cancer post-operative stage based upon pre-treatment quantitative biopsy pathology as well as DNA ploidy and quantitative nuclear grade information determined by image analysis. The product was Trademarked "UroScore™", a term suggested by Dr. Veltri. There are three publications (reference # 51, 77 and 88 in the above bibliography) on the subject.

In 2002, Dr. Veltri accepted the appointment as Visiting Associate Professor of Urology at the Johns Hopkins University School of Medicine. He is currently directing a research Laboratory conducting research on diagnostic and prognostic biomarkers for urologic cancers using Quantitative Computer-Assisted Image Analysis to study nuclear structure and Proteomics technology (SELDI-TOF, 1D and 2D Electrophoresis, ELISA, Immunohistochemistry etc.).

In 2003, November 1, Dr. Veltri was appointed as a Full-time Associate Professor of Urology at The Johns Hopkins University School of Medicine. He continues to direct research on biomarkers for prostate, bladder and renal cancer using a image cytometry-based and proteomics-based approach.